

KASPER implementation. Those who do perceive a change are nearly equally divided between an increase and decrease in dispensing. Overall, the majority of respondents believe that KASPER is an effective tool to reduce drug abuse, diversion, and doctor shopping. Further research is necessary to assess the full effectiveness of PDMPs.

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THE US ORPHAN DRUG LANDSCAPE: BEFORE AND AFTER EU ORPHAN DRUG LEGISLATION OF 2000

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OBJECTIVES: To encourage the development of orphan drug (OD) products, the European Union (EU) approved OD legislation in 2000, mirroring the US legislation passed in 1983. For the first time in history, these products were recognized as different from other drug products on a global level. Given this new global incentive for OD development, an increased focus on developing these products was expected. The objective of this research is to quantify a change in the rate of global OD development as measured by the rate of US Food & Drugs Administration (FDA) OD designations. **METHODS:** All history within the OD database from the FDA website was included. The OD status, designation date, and contact company fields were analyzed to evaluate the OD designation rate and location of developers (US or non-US categories). **RESULTS:** There was a sharp increase in the number of FDA OD designations after the year 2000, with the rate of OD designations increasing by 475% compared to the prior period. From 1983 until 2000, 516 products received an FDA OD designation and the average increase in OD designation was 2.5 per year. From 2000 through 2011, the number of designations was 1266 and average increase in OD designation was 14.7 per year. After 2000, the proportion of OD designations from non-US countries increased until 2009 when nearly one-third of products with a new FDA OD designation were from non-US companies. **CONCLUSIONS:** The implementation of EU OD legislation may have contributed to a change in the number of FDA OD designations per year and the types of companies developing ODs for the US. With developing markets preparing OD legislation, these policy changes may further stimulate the growth of the OD industry around the world.

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PRESCRIPTION MONITORING PROGRAM EFFECTIVENESS: PERCEPTIONS OF DRUG DIVERSION INVESTIGATORS

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OBJECTIVES: Most states have implemented prescription drug monitoring programs (PDMPs) to reduce prescription controlled substance (CS) abuse and diversion. Relatively little is known, however, about their effectiveness in achieving these goals. The purpose of this project was to assess the perceived impact of the Kentucky All Schedule Prescription Electronic Reporting program (KASPER) on CS abuse, diversion and doctor shopping. **METHODS:** All law enforcement officials in Kentucky with an active KASPER account (1119) were surveyed via email. Three hundred forty (340) responses were received yielding a response rate of 30%. Responses were coded and descriptive analysis was conducted in STATA v11. **RESULTS:** Nearly all (99%) law enforcement officials indicated that they had utilized a KASPER report in the past and, on average, request 3.8 reports per month for use in drug diversion investigations. When asked for their opinion on how KASPER has affected health care provider behavior, the majority (70%) believed that pharmacists had not altered the stocking and dispensing of CS; however, respondents were split on their opinion of prescriber behavior. Nearly half (45%) thought prescribers had altered their prescribing of CS. With respect to law enforcement use of KASPER reports as an investigative tool, 67% of respondents indicated that information contained in the report confirmed their decision to proceed with an investigation while 14% stated that the report caused them to close or dismiss pursuit of an investigation. Most (93%) respondents believe KASPER is an effective tool for reducing abuse and diversion while 90% believe it is an effective tool to reduce doctor shopping. **CONCLUSIONS:** Law enforcement officials believe that KASPER reports are a valuable tool when conducting investigations. Overall, the vast majority of respondents perceive KASPER as an effective tool to reduce drug abuse, diversion and doctor shopping. Further research is needed to directly assess the effectiveness of PDMPs.

HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

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EXAMINATION OF VALUE DRIVERS IN THE ADOPTION OF WELLNESS PROGRAMS FOR CHRONIC DISEASES

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OBJECTIVES: A growing global concern is the substantial prevalence of avoidable chronic disease states, which account for more than 75% of US health care expenditures (CDC, 2010). In response, the utilization of wellness programs by stakeholder groups to address modifiable risk factors for chronic disease states has increased. However, the broad variation in perceived value drivers by stakeholders has influenced widespread wellness program adoption. This study was undertaken to identify and evaluate critical clinical and economic drivers of wellness technology and program adoption. **METHODS:** A comprehensive review of wellness program design, utilization, and adoption drivers was conducted. Subsequently, an in depth interview program of US stakeholders including payers, clinicians, employ-

ers and wellness program providers was performed. The interviews were designed to evaluate stakeholder perceptions of value drivers and measurements of wellness program benefit. **RESULTS:** Our data suggest that effective drivers of wellness program adoption are measurable with defined clinical or economic benefit(s). Optimizing technology utilization, altering negative patient behaviors and incentivizing patient adherence are key factors in this regard. However, stakeholder perceptions regarding the identification and evaluation of wellness program success measurements varied substantially. Moreover, stakeholder alignment regarding these measurements may be a key driver of program adoption. **CONCLUSIONS:** This study suggests that the demonstrated clinical and economic impact of wellness programs influence perceptions of value. Despite wellness programs trending towards addressing cardiovascular disease, diabetes and metabolic syndrome/obesity, harmonization of program evaluation criteria has not emerged. Program adoption is can be affected by the lack of aligned perceptions of value within stakeholder groups. Properly aligned metrics of clinical and economic benefit along with optimization of technology utilization, patient adherence and return on investment are critical drivers of wellness program adoption. Guidance is needed on efficient measures of clinical and economic outcomes to improve design and adoption of wellness programs.

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PERCEPTIONS ON PAYER-INDUSTRY PARTNERSHIPS IN INFLUENCE COUNTRIES

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OBJECTIVES: This study sought to understand the current use of payer-industry partnerships in key influence markets and to gain insight into regional perspectives on the current and future use of payer-industry partnerships. **METHODS:** Primary research was conducted through 57, 30-60 minute interviews of key stakeholders from industry and regulatory agencies across 9 major markets (EU 5, United States, Japan, Canada, and Australia). Interview questionnaires were designed to understand perceptions regarding current partnerships as well as awareness of emerging models. Primary data was complemented by reviews of published and gray literature, government and other relevant agency websites, and IHS proprietary Healthcare and Pharmaceutical content. **RESULTS:** Two broad categories of partnerships were predominantly used across the countries examined – partnerships for reimbursement decision-making (e.g. risk-sharing agreements) and partnerships downstream of reimbursement (e.g. disease management programs). One key finding was the acceptance of payer-industry partnerships as a necessary practice as opposed to short term trend. According to interviewees, partnerships are increasingly becoming a necessity because of gaps in funding. Given such challenges, stakeholders are more willing to consider novel opportunities for collaboration with industry. Secondly, this study found a lack of agreement on the preferred type of payer-industry partnerships. For example, the United States has used disease management systems and other downstream partnerships as a mainstay. Payer sentiment, however, is that these practices are flawed, with many US stakeholders looking to risk sharing for future partnerships. Conversely, many stakeholders in the UK have expressed interest in moving away from risk sharing to adopt more downstream partnerships. **CONCLUSIONS:** Payer-industry partnerships are making the transition from being experimental options to permanent practice within health care systems. Countries are looking at methods used in other regions to explore new opportunities to expand partnerships. There is a lack of international alignment, however, on which partnerships will be most beneficial in the future.

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THE FUTURE OF ALTERNATIVE PRICING/RISK-SHARING AGREEMENTS IN THE UNITED STATES

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OBJECTIVES: Due to the rising cost of health care in the United States, payers have begun to place an increased emphasis on cost when evaluating new submissions for formulary access. Our objective was to evaluate the US payer perception of alternative pricing/risk-sharing (AP/RS) agreements focusing on: 1) assessing the success of previously implemented AP/RS agreements in the United States, and 2) evaluating conceptual AP/RS structures with payers to assess preference of concepts. **METHODS:** An online survey was conducted to evaluate the perceptions of a broad spectrum of US payers on AP/RS agreements (n=19). Following the survey, in-depth interviews (n=5) were conducted with US national and regional payers to gain additional insight. **RESULTS:** More than 90% of US payers were interested in AP/RS agreements. Payers believed that these types of agreements could be implemented for both their pharmacy (84% of payers) and medical (42% of payers) benefits. Over half the payers (52%) believed that AP/RS agreements should be considered for orphan diseases, 68% believed that they should be considered for other rare diseases, and 73% believed that they should be considered for chronic high-prevalence diseases. Payers expressed concerns that previous AP/RS agreements were not successful due to a lack of independent data reporting and an imbalance in risk-sharing. Payers (73%) showed a preference for “pay-for-performance” schemes that offered predictable cost outlays and mutually beneficial risk agreements with clearly-defined and independently-verified success markers. **CONCLUSIONS:** US payers are keenly aware of alternative pricing/risk-sharing agreements and foresee them playing a larger role in future US negotiations if clear cost and risk benchmarks are established.